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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/940,471      | 08/27/2001  | William J. Rissmann  | 032580.0018.UTL     | 5252             |

21691 7590 01/13/2005

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MINNEAPOLIS, MN 55403-2420

EXAMINER

MULLEN, KRISTEN DROESCH

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

3762

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/940,471 | <b>Applicant(s)</b><br>RISSMANN ET AL. <span style="float: right;">CR</span> |  |
|                              | <b>Examiner</b><br>Kristen Mullen    | <b>Art Unit</b><br>3762  |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 192-206 and 208-217 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 201-205, 209-211 and 213-217 is/are allowed.
- 6) ☒ Claim(s) 192-200, 206, 208 and 212 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 206 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams (5,441,518). Adams shows a method comprising implanting a device having a power source and an energy storage system into a patient; providing a lead system having one or more electrodes (14) for the device, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart; coupling the energy power source to an energy storage system; storing energy in the energy storage system and discharging the energy from the energy storage system to the patient, the step of discharging the energy including using at least one electrode disposed in the lead system (14); wherein the step of discharging the energy uses a first electrode (14) that is part of the lead system and a second electrode (11) disposed on the device itself, wherein the amount of energy discharged is selected to achieve a defibrillation function.

3. Claims 208 and 212 are rejected under 35 U.S.C. 102(b) as being anticipated by KenKnight (6,148,230). A method comprising providing a lead assembly including a first electrode (22, 24) implanted in a patient, the lead assembly provided such that it does not contact the patient's heart; providing a device including a battery and a means for storing energy, the device being coupled to the lead assembly; providing a second electrode (18) implanted such that it does not contact the patient's heart; sensing far-field

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signals using a sensing electrode pair including the first electrode (22, 24) to monitor a portion of the patient's cardiac rhythm; determining whether the patient's cardiac rhythm requires electrical therapy; and, if so: supplying energy from the battery to the energy storage means; and discharging energy stored in the energy storage means to the patient using a stimulus electrode pair including the second electrode (11); wherein the second electrode is provided on a housing of the device (Fig. 1).

With respect to claim 212, KenKnight shows the lead (20) extends medially from the device (Fig. 1).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 192-199 are rejected under 35 U.S.C. 103(a) as being unpatentable over Causey III (5,411,547) in view of Bennett et al. (5,331,966).

With respect to claim 191, Causey III shows a method of supplying energy for alleviating a cardiac dysfunction comprising: implanting a device having a power source and an energy storage system into a patient; providing a lead system having one or more electrodes, the lead system provided such that it is disposed internally to a patient without contacting the patient's heart; coupling the power source to the energy storage system; storing energy in the energy storage system; and discharging the energy from the energy storage system to the patient, the step of discharging the energy including using at least one electrode (24, 26) disposed in the lead system; wherein the step of sensing an

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abnormality further includes determining whether the patient has an abnormally slow heart rate (asystole) (Col. 1, lines 36-39; Col. 3, lines 28-53) (Fig. 4). Although Causey III fails to show sensing an abnormality in the patient's rhythm using electrodes disposed internally to the patient but not contacting the patient's heart, attention is directed to attention is directed to Bennett et al. which teaches an implantable stimulus device with electrodes located on the device housing to sense arrhythmias. Bennett teaches that providing multiple sensing electrodes (A, B, C) on the device housing provides a leadless orientation insensitive means for receiving electrical signals from the heart (Abs). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device housing and method of Causey III Adams with the device housing incorporating sensing electrodes as Bennett et al teaches in order to provide a leadless orientation insensitive means for receiving electrical signals from the heart.

Regarding claim 192, Causey III shows providing a lead system such that it does not reside in the patient's vasculature (Fig. 4).

With respect to claims 195, Bennett further shows sensing, and abnormally slow rate (bradycardia), and ventricular fibrillation.

With respect to claims 196-197, Causey III further shows determining if the patient has an abnormally fast heartbeat or determining if the patient is likely experiencing defibrillation (Col. 1, lines 36-39).

Regarding claim 198, Bennett shows the electrodes are part of the lead system (Fig. 2c).

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Regarding claim 198, Causey III shows the electrodes (24, 26) are part of the lead system (Fig. 4).

With respect to claim 199, Causey III shows at least one of the electrodes (24, 26) in the lead system is also an electrode used for discharging energy (Fig. 4).

6. Claim 200 is rejected under 35 U.S.C. 103(a) as being unpatentable over Causey, III (5,411,547) in view of Bennett et al. (5,331,966) and further in view of Bardy (5,292,338). Causey III and Bennett et al. are as explained before. Causey III and Bennett et al. fail to specifically point out that the defibrillator is implanted subcutaneously between the third rib and the twelfth rib of the patient, but only mentions that a known defibrillator is used. Attention is directed to Bardy, which teaches a known defibrillator that is implanted in the left infraclavicular pectoral region. As seen in Fig. 2 of Sanchez, Zambrano (5,895,414) the clavicle (21) is located approximately at the same location or level as the third rib (23) in the pectoral region. Thus, if the known defibrillator Bardy is implanted in the left infraclavicular pectoral region, it is advanced below the third rib and above the twelfth rib. Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to implant the defibrillator of Causey III and Bennett et al. subcutaneously between the third rib and the twelfth rib of the patient as is known for implanting known defibrillators.

#### ***Response to Arguments***

7. Applicant's arguments with respect to claims 192-200, 206, 208, and 212 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Allowable Subject Matter***

8. Claims 201-205, 209, 210-211, 213-215, and 216-217 are allowed.

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***Conclusion***

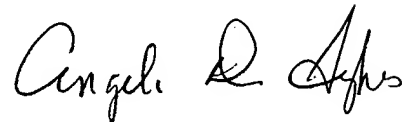
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



kdm



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